

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the *prior art reference* must teach or suggest all of the claim limitations. (MPEP § 2142).

Applicants respectfully assert that their claims 1-16, 23 (in part) and 27-28 are not obvious under 35 U.S.C. § 103 in view of the stated prior art. The Examiner states that Jandaceck, Akoh and the FDA announcement abstract taken together, do not teach the combination of beta glucan polyol fatty acid esters in a food composition and their particular amounts. Therefore, the prior art references do not teach or suggest all of the claim limitations, namely the ratios and amounts of beta-glucan and non-digestible fat used. The Examiner asserts in her office action that it would have been obvious for one of ordinary skill in the art to employ beta-glucan and a non-digestible fat in the amounts claimed herein.

Applicants respectfully point out that the Examiner has misapplied the test for obviousness. The third prong of the test for obviousness specifically requires that the *prior art references* teach or suggest all of the claim limitations. As noted in the Examiner's own admission, the prior art references do not teach Applicants' amounts and ratios of their beta-glucan and non-digestible fat in combination. The third prong of the test for obviousness then fails; the Examiner has therefore failed to present a prima facie case of obviousness for those claims reciting the beta-glucan and non-digestible fat levels in combination together, namely claims 2, 3, 4, 5, 6, 7, 11, and 13.

The Examiner further argues that it would have been obvious to one of skill in the art to create Applicants' invention because both beta-glucan and polyol fatty acid esters are known to provide anti-hypercholesterolemic effects. The Examiner cites and relies on the holding of *In re Kerkhoven* which states the following: "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose."

Applicants again respectfully disagree with the Examiner's contention. First, beta-glucan and a non-digestible fat are combined by Applicants not just to deliver an anti-hypercholesterolemic effect. The beta-glucan is used primarily for this purpose, but the non-digestible fat is used primarily for the purpose of providing the benefit of an appealing taste and

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texture to the beta-glucan or the source thereof. In their disclosure, Applicants are clear on this point and at page 11, lines 16-19 state the following:

In one mode, beta-glucan soluble fiber or a source of beta-glucan soluble fiber and a non-digestible fat are combined with other materials to form embodiments that have the form of appealing foods, and that, in many cases, are as appealing in their taste and textural properties as many conventional snack foods.

Additionally, Applicants make note of the problems with the taste and desirability of the use of beta-glucan and sources thereof in food products notwithstanding the known health benefits of the anti-hypercholesterolemic effects. At page 4, lines 19-21 Applicants state that “what is needed, in addition to compositions comprising beta-glucan soluble fiber and a non-digestible fat, is one or more foods comprising beta-glucan soluble fiber and a non-digestible fat, wherein the food has the form, and preferably the taste and texture, of an appealing but unhealthy food.” Applicants further note in their disclosure that unfortunately, the incorporation of various beta-glucan containing ingredients into food products results in challenging taste and/or process performance issue (pg. 4, lines 22-23). Applicants’ answer to the problems with beta-glucan is to combine it in proscribed amounts to a non-digestible fat.

Applicants’ combination of beta-glucan with a non-digestible fat in proscribed amounts is an answer to the long felt but unmet need of producing beta-glucan filled foods that are appealing and have a good taste and texture. The beta-glucan provides the anti-hypercholesterolemic benefit but the non-digestible fat provides the appealing taste and texture benefit. The two components combined provide an appealing dietary composition for reducing cholesterol in a food form with appealing taste and texture.

*long-felt need*

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. (MPEP § 716.04). Long felt need is governed by three objective factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art--namely, making beta-glucan and sources thereof into appealing forms for taste and texture. (*In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967)). Second, the long-felt need must not have been satisfied by another before the invention by Applicants--namely, that no one else save Applicants has taught or suggested combining beta-glucan and a non-digestible fat for appealing taste and texture. (*Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988)). Third, the invention must in fact satisfy the long felt need--namely, that Applicants’ invention works and provides an appealing taste and texture for consumers seeking to consume

foods providing an anti-hypercholesterolemic benefit that tastes "good". (*In re Cananagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971)).

Applicants respectfully assert that their solution to the long felt but unmet need of providing beta-glucan in an appealing form has not heretofore been solved or suggested. Furthermore, Applicants assert that there is no motivation in the prior art nor in the knowledge of those of skill in the art to have combined beta-glucan with a non-digestible fat to create an appealing composition with anti-hypercholesterolemic benefits.

Additionally, Applicants assert that their combination of beta-glucan with a non-digestible fat are combined not for the same reason (i.e., the anti-hypercholesterolemic effects) but rather for two separate purposes as has been discussed herein throughout. For this reason, their combination falls outside of the holding of *In re Kerkhoven*.

In light of the foregoing discussion, Applicants respectfully request re-consideration and allowance of claims 1-16, 23 (part of), and 27-28 over the Examiner's 35 U.S.C. § 103(a) rejections.

#### SUMMARY

All of the rejections in the Office Action have been discussed as have the distinctions between the cited references and the claimed invention.

In light of the discussions contained herein, Applicants respectfully request reconsideration of the rejections and their withdrawal, and all of the claims allowed.

Issuance of a Notice of Allowance at an early date is earnestly solicited.

Respectfully submitted,

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